

PSJ10 Exh 63

# A Watson Pharma, Inc.

## ***Call Center Operations*** ***Master Data / License Admin. Operational Procedure***

<b>PROCEDURE:</b>	<b>License Maintenance</b> <b>Create, Change License or Create, Change Listing/Exclusion for Controlled and Non-Controlled substance License</b>		
<b>Written by:</b>	Karen Schomer	<b>Date:</b>	05/03/04
<b>Call Center Policy Number:</b>	<b>GUROPDALAR 507001.003</b>	<b>Policy Effective Date</b>	May 3, 2004
<b>Revision written by:</b>	Larry Shaffer Mary Moskello Victoria Lepore	<b>Revision date:</b>	January 5, 2012
<b>CTM Transaction:</b>	VX01N- License Create VX02N- License Change VB01- Create Listing / Exclusion VB02- Change Listing / Exclusion VE30- Existing Licenses VE31- License Blocked Sales Orders VCH1- Create Batch Search Strategy VCH2- Change Batch Search Strategy	<b>CTM Doc #</b>	
<b>Prerequisites SAP Transaction Code</b>	VD01- Create Customer VD02- Change Customer		
<b>Post réquisits SAP Transaction Code</b>			

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### Purpose

Establish and maintain the proper method of applying licensing information on an account to ensure compliance with the Drug Enforcement Administration (DEA) licensing requirements and the Prescription Drug Marketing Act (PDMA), as well as, the National Association of Boards of Pharmacy.

### Scope

All Call Center Operations employees directly or indirectly responsible for customer account maintenance

### Procedure

Once a customer account has been opened, updated, or unblocked, the Master Data Administrator (MDA) will review and verify the licensing information for accuracy.

All information necessary for analysis, review and validation of a license must be submitted to the SAP Master Data Administrator (MDA).

The following information is verified against the current License for accuracy:

1. Customer Name
2. Ship-To Address

Note: Ship-to address MUST match the DEA License. However PDMA regulations policy to ship non-controlled sample products only to a facility that the requesting practitioner operates from. If the address of the licensed practitioner does not match the address of the practitioner's license, then the MDA and/or CRA/SAA must verify that the practitioner does practice at the Ship-to address. Verification of the practitioner address may be done by obtaining a

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copy of the doctor's valid state license, a phone call to the facility, finding the location on the internet via the yellow pages or comparable search engine, or avoided Rx that shows the practitioner at the Ship-to.

3. DEA number / State License
4. DEA expiration date / State License expiration date
5. Approved Drug Schedule(s)

Please take note: Accounts are not deleted or de-activated. When an account is no longer in use, i.e. per customer request, location has moved, or any other reasons, the MDA will block the account and expire all current licenses attached to the account. Also the MDA will report to the Board of Pharmacy, FDA and DEA in 3 business days if unable to authenticate the vendor/customer.

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### **A. DRUG SUBSTANCES – Controlled:**

#### **1. DEA License**

DEA license is required for orders containing controlled substances. The DEA license includes the DEA license number, DEA license expiration date and the approved drug schedules (2, 2N, 3, 3N, 4, 5).

Schedule	Regulatory Definitions
2	High Potential for abuse. Use may lead to severe physical or psychological dependence. No renewals are permitted
2N	Same as above except, Non-narcotic
3	Some potential for abuse. Use may lead to low to moderate physical dependence or high psychological dependence. Up to 5 renewals are allowed within 6 months.
3N	Same as above except, Non-narcotic
4	Low potential for abuse. Use may lead to limited dependence either physically or psychologically. Up to 5 renewals are permitted within 6 months.
5	Subject to state and local regulation. Abuse potential is low; a prescription may not be required.
Rx	Prescription (SAP requirement)

Verification of the DEA license number, DEA shipping address, and DEA expiration date and drug schedule can be made by:

- Using The U.S. Department of Commerce National Technical Information Services (NTIS) Drug Enforcement Administration (DEA) website: <http://deanumber.com/> (See Exhibit A).
- Obtaining a photocopy of the DEA license certificate from the customer or on the website DEANUMBER.com (NTIS).

If the copy received from the customer is not legible and does not exist on the DEA website (NTIS) or the DEA license has expired, the MDA will leave the order on license block in SAP, until the appropriate documentation is received. The MDA will contact the customer or the CRA responsible for the account to request a valid/current photocopy of the DEA License. The MDA will update the account upon receipt of a valid DEA license to remove the block on the order in SAP. The MDA will also communicate and report back to the Customer Support department on the licensing status, if necessary.

If the photocopy of the DEA License is not received, the MDA will contact the customer or the CRA responsible for the account a second time requesting the photocopy of the DEA license. If the photocopy of the DEA license is not received, the customer will be notified that the pending order will be cancelled until a valid DEA license is received. The MDA will update the account with an overall block until a valid license has been received. Once a valid license has been received the overall block will be removed.

\*NOTE: Only the schedules (2, 2N, 3, 3N, 4, 5) that are registered and shown on the license will be created in SAP. Also, customers with a DEA license automatically receive schedule Rx.

Retail Outlets and Practitioners must register all schedules to receive shipment.

The check digit algorithm will determine the validity of a DEA number. The seventh digit of the DEA number is the Check Digit. Add the first, third, and fifth digits to equal SUM1. Add the second, fourth, and sixth digits and then multiply by 2 for Sum2. Add SUM1 + SUM2. The last digit of this total should equal the seventh (Check Digit) of the DEA #.

Note: On occasion DEA licenses with only 1 letter at the beginning (i.e. R10184159) may be submitted. These licenses are usually submitted by customers that have a name that starts with a number (i.e. 212 Pharmacy). The check digit algorithm can still be used by treating the first number as the 2<sup>nd</sup> letter of a typical DEA license. If necessary, the DEA can be called directly to verify the validity of a license.

DEA check digit algorithm								Results	
For example: DEA License RW0184159									
DEA	First	Second	Third	Fourth	Fifth	Sixth	Seventh (check digit)		
RW	0		8		1		9	9	Sum1
		1		4		5		10 x 2 = 20	Sum2

#### **2. Creating Exclusion Record**

Three exclusion methods are currently being used, Customer/Schedule Number, SalesDocType/Ord.reason/Sch No., and Customer/Material. The Customer/Schedule Number exclusion is set up is when the customer requests to exclude schedules. The customer may request to exclude schedules because the facility does not have proper storage and/or when the customer does not wish to receive those schedules. The SalesDocType/Ord.reason/Sch No. is setup when it is decided that a specific Order Type (i.e. Standard Order) and Order Reason (i.e. Drop ship) should not receive certain schedules. The Customer/Material is used the when specific materials will not be ordered/shipped to a specific customer.

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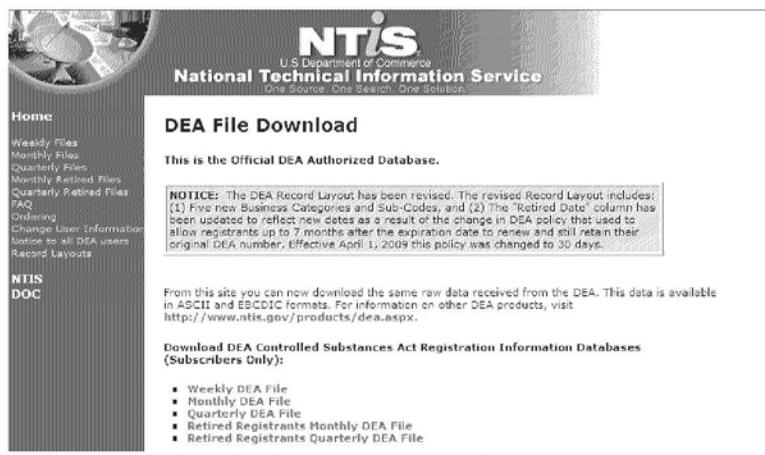
### **3. Violations**

The Master Data Administrator (MDA) will review and release sales orders pending licensing verification. This is critical in order to remain in compliance with the DEA, State and PDMA law as it pertains to the sales and distribution of pharmaceutical products.

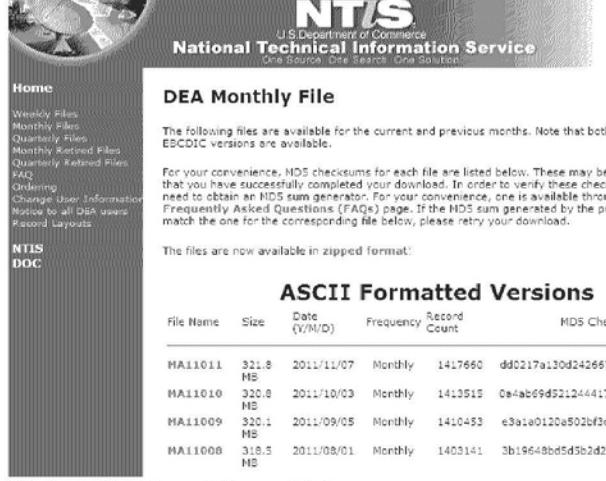
### **4. NTIS Disc**

The Master Data Administrator (MDA) will download the NTIS file from the NTIS website on the first business day of the month; Go to [www.DEA.NTIS.GOV](http://www.DEA.NTIS.GOV)

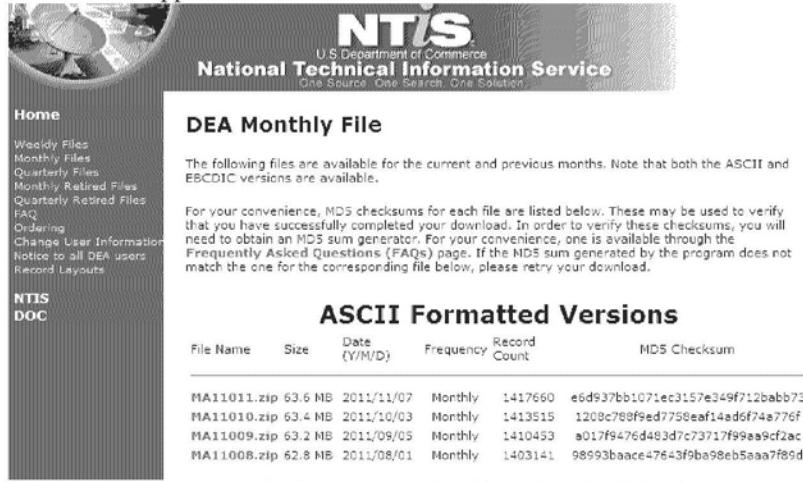
The link and the password for the following website will be on the portal  
Go to [www.DEA.NTIS.GOV](http://www.DEA.NTIS.GOV)  
The screen will look as below:



Go to the "monthly file" link either to the left column or the bottom.



Click on the zipped format link.



Click once on the first file that starts with MA and ends with .zip  
This brings up as sign on screen:

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The server dea.ntis.gov at DEA Monthly Access requires a username and password.

User name:	<input type="text"/>
Password:	<input type="password"/>
<input type="checkbox"/> Remember my password	
<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Enter the following information:

Username: 525246

Password: Watson! 2011

Checking the remember password is optional

Click OK

Save file anywhere, usually desktop

Go to the location where you saved it (usually desktop)

Right click on the file and click on extracting all, Click Next

Click OK (the default location is the desktop)

Click Finish

Now open the Customer Master folder and then the sub-folder NTIS File

- Customer Master
  - 1 Pending (Initial request)
  - 3 Pending (Accounting)
  - 4 Pending (Contracts)
  - 5 Pending (License)
  - 6 Pending (Notify requestor)
  - Accounting Completed 2004
  - CARS Tools
  - Compensation
  - Completed
  - CUSTLISTS
  - Drive Shortcuts
  - Licensing Department
  - MEMBERSHIP
  - MISC
  - NTIS File

Click on the location where you stored the recent NTIS file (usually desktop) and drag the file to the NTIS File folder.

Copy the path for this location as below:

V:\Sales Operations & Distribution\Customer Master\NTIS File

Send an email to the IT Dept along with the record count (found on the screen when you clicked on the "Monthly Files" on the original website). Make the subject of the email "NTIS File".

Once the file is loaded into SAP by the IT Dept., it will then be filed in Corona, CA with past NTIS Discs.

\*NOTE: On a monthly basis, the DEA registration file information is loaded, by the Information Systems group. The updated information is in accordance with information on file at the DEA. This is inclusive of DEA license expiration date and authorized schedules. However, the DEA registration file information may not be as current as the DEA website mentioned above. The most current data should be used. Please see the Information Systems group update process below:

### **Monthly DEA License Update from NTIS CD Process**

1. **Prod Support executes a trial run in a test system** – this is not done to update the license values in the test system, rather to determine whether there are any format or data problems with the CD. In the past 14 months we have had circumstances in which a) dates on the CD were incorrectly formatted and b) schedule values on the CD were not valid (licenses with Schedule 1). It is important to discover these errors and request a replacement CD from NTIS prior to using the CD to update the production system.
2. **Prod Support executes the custom License Update program in the production system** – a brief summary of the functionality of the program:

**Custom Program Name:** ZVI\_DEA\_LICENSE  
**Transaction Code:** ZVLICUPD

The program selects all active DEA license records from the SAP system. Each record is then matched against the NTIS CD using DEA number, if found, the end dates and schedules of the SAP license and the NTIS entry are compared. If they are identical, no updates are made

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in SAP. If they are different (i.e., new end date, different schedules), the existing SAP license is expired and a new license is created using the values from the NTIS entry. If a match is not found, the SAP license is expired, as the validity of the license could not be confirmed with the NTIS file.

The program also dumps the full content of the NTIS file into a custom SAP table ZVDEA for reference purposes. After completion of the job, the number of records in this table is compared to documentation received with the file to confirm that the record counts match. This is done via transaction code ZVDEA.

If errors occur during the execution of the job, Prod Support will analyze and correct the errors. The job is usually executed Friday evening, so that errors can be resolved with limited impact to the business.

3. **Post Processing Reporting** – after processing is complete, Prod Support produces a listing of expired and new licenses, using the SQVI Quick viewer query tool in SAP. The listing shows all licenses expired; and, if a new license was created (in the case of updates). This listing is sent to the Master Data Team for review.

**Notes:** One issue regarding this process is that a time lag will always potentially exist between receipt/application of the CD and the actual status of the DEA licenses. The Licensing team has access to daily updated information on DEA licenses via the internet, including newly created licenses; they will capture and create/update licenses in the SAP system based on business requirements. However, as noted in the processing summary, if the CD does not contain a license (i.e., perhaps a license just created/approved in the past week, after the latest CD was mailed), the program will consider it invalid.

The Post Processing listing also contains information about the Created On date and Created by ID of a license. One possibility is for the Master Data Team to review the list by the Created on date, so that expired licenses that were created most recently will be readily apparent. These are the most likely to have been created/updated after the CD was issued, and the Master Data Team can manually update them before any business impact is realized. If the license continues to be missing from the CD month after month (requiring manual re-creation), this should be researched; supposedly, if it's not on the file it doesn't exist.

Licenses used on specific orders: this is not related to the update process in any way; however, this data is available via standard SAP transaction ENGK, using the Assigned Documents option under Alert Reporting. Among the search criteria available are license type, license number (internal SAP or external/DEA number), and Sold-to customer and schedule number.

### **5. Licensing Issues**

Whenever there is a discrepancy between the information on the licensing website and the account, for example, the customer has recently moved to another address, but the website still reflects the old address. The Customer Relations Administrator should then contact the customer to verify the correct information and obtain the supporting documents. If the account needs to be changed, the CRA/ Specialty Account Administrator will need to fill out the appropriate form and submit according to standard procedures. If the Master Data group cannot update the address on the account within 48 hrs, then the Master Data group should EXPIRE the current license. Once the Master Data group has followed the procedure to correct the address in SAP then validate and re-instate the license according to standard procedures. If the customer has a new license number, then the current license should be expired immediately and a new license should be created according to standard procedures.

#### Validating Medical Prescriber's State Licenses

The Master Data Administrator will validate the State License using the PRS website.

In the event PRS is not up to date, the Master Data Administrator visits the respective state website. If the PRS and state website reflect an expired license, MDA will notify the CRA/SAA. The CRS/SAA will need to contact the customer to provide an updated license.

### **6. TIRF REMS REGISTRATION**

The goals of the TIRF REMS Access Program are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients.
- Preventing inappropriate conversion between fentanyl products.
- Preventing accidental exposure to children and others for whom it was not prescribed.
- Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose of TIRF medicines.

Effective March 12, 2012, Sold-to (corporate locations) making a direct purchase from the manufacturer are required to have a distributor registration in order to purchase and receive the following Fentanyl Citrate EQ Oral Trans sku's.

55253007430	FENTANYL CITRATE EQ ORAL TRANS 1200MCG30
55253007530	FENTANYL CITRATE EQ ORAL TRANS 1600MCG30
55253007030	FENTANYL CITRATE EQ ORAL TRANS 200MCG 30
55253007130	FENTANYL CITRATE EQ ORAL TRANS 400MCG 30
55253007230	FENTANYL CITRATE EQ ORAL TRANS 600MCG 30
55253007330	FENTANYL CITRATE EQ ORAL TRANS 800MCG 30

The registration is compliant for all of the SH locations associated with the Sold-to.

The Master Data Administrator (MDA) will access the **TIRF REMS Access Program** website <http://www.tirfremsaccess.com/TirfUISplashWeb/index.html> every Monday of each week.

Enter the following information:

Username:

Password:

Checking the remember password is optional???

Click OK???

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You will have access to the following tabs in the **TIRF REMS Access Program**:

- **Enrolled** – participants that are enrolled in the TIRF REMS Access program
- **Incomplete** – ignore this tab, not necessary to view
- **Deactivated** – customers opt out of the program
- **Choice of Pharmacy** – ignore this tab, not necessary to view
- **Distributor - )**

The participants that were enrolled in the Actiq/Fentora program will be grandfathered into the TIRF REMS ACCESS program,, they will be enrolled under the “distributor section” under the enrolled tab.

If the participant party opts outs , or does not register to participate in the TIRF REMS Access Program, you can locate the data under “distributor” **deactivated** tab.

When the customer’s registration is within 90 days of expiration, they will receive notice for renewal. Verify the new effective dates at the “distributor section” under the enrolled tab.

There are different scenarios for the REMS program but not limited to:

- If there is a new SP that is participating in the REMS program, you need to create a REMS registration from the valid date of the registration and the valid to is good for two years from that point that the registration was received.
- You need to verify that there is true SH’s at the Sold-to level that orders controls. Each SH must be a entity of the Corporate Office. For example, American Health Packaging and Testpak are repackagers and they shouldn’t be included in the REMS registration.
- If the Sold-to no longer participates in the TIRF REMS Access Program, you need to expire the REMS registration and add notes in the comment field that SP is no longer participating in TIRF REMS Access Program. There is no need to add exclusions since the REMS registration will be expired.
- If an order is placed for a participant that is no longer in the program, the order will go on license block. You can verify by SH location, that there was a REMS registration and the comment notes will show the reason for the expired registration.
- If there is an order that goes on license block, you will need to check the **Legal Control Issue Error Log Item** to view the reason for the block. It could block be either for DEA or, State license and/or REMS registration. Look at the order and see what products are being ordered before going to the error log. If you notice it is Fentanyl products, than it is highly likely that it is due to a REMS registration issue.
- If the license block is for REMS, you need to search by SH location to see if there is a REMS registration and if there is, you need to check if the SH location was added to the registration.
- If the REMS registration is expired, you will need to contact the Customer Relations Administrator to handle.

NOTE: The external registration is “TIRFREMS” for all of the participating parties that have a REMS registration.

### **7. Health Identification Number (HIN)**

If the HIN is being used, the Contracts Department need only submit the HIN. No additional documentation is required. The Master Data Administrator (MDA) will populate the current date in the “valid from” field and 12/31/9999 in the “valid to” field. On the ExpContrClass tab there is no need to include schedule numbers when creating a HIN, this field will be left blank. On the Customers tab, the MDA will need to add the customer account number and then accept the license under the Status tab. Input the SAP internal license number on the spreadsheet provided. Once all the HIN numbers have been created the updated spreadsheet needs to be forwarded to the Contracts Dept. if requested.

### **8. License blocks**

The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to license violations are investigated. Once the investigation has been completed the MDA will take the appropriate action necessary to either release the sales order hold or notify the appropriate Order Entry representative regarding the necessary action required in order to update the license. If customer contact is necessary to obtain a valid license, the MDA will make an attempt to contact the customer to obtain a valid license. If the MDA is unable to obtain a valid license after contacting the customer, the MDA will notify the CRA/SAA and the CRA/SAA will contact the customer to obtain a valid license. For example, if the order went to License Block (VE31) and the MDA noticed that the customer cannot receive 2 and 2N on their license, the MDA would notify the CRA responsible for that account (and Order Processing, if necessary) that the customer is not able to receive the product they ordered. This usually happens when it is an EDI order or sample order. Note: For IMA customers, when an order is on VE31 and IMA block; and the MDA goes into the order to release it they will see a pop up message that states the order is on IMA block, do not make ANY changes. The MDA should back out of the order immediately and do not save any changes. The MDA must wait until the order is released from the IMA block before releasing the order from VE31 License Block; otherwise this will cause an error with the order. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Watson in order to streamline their inventory.)

### **9. CII Schedule Drugs and SOMS blocks**

#### **SOMS – Suspicious Order Monitoring System (Of Control Drugs Substances)**

The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to suspicious order violations (SOMS) are investigated. The MDA will execute VA05 to determine the value and priority of the orders blocked due to SOMS violations. A MDA will print the SOMS form. The SOMS form contains Class of Trade (COT) averages and customer allowable/order and customer allowable/month.

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The MDA will review the SOMS form to determine if customer contact is necessary. If customer contact is necessary, the MDA will contact the customer. If necessary, the customer contact information can be obtained from the CRA responsible for the account. The MDA will contact the customer to determine if the order should be considered an 'order of interest'. If the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation. All orders that require additional analysis should be communicated to the appropriate CRA and CRA Manager.

The following procedure is used to identify if the order is at or over the allowance Watson gives the customer which will assist in determining the degree of analysis needed to release the order. Each order is evaluated and the best release code is applied to each order at that time.

Put the number that's in the "Order Quantity" column into the "Release Qty" column. Then, mathematically ADD the following columns "MTD Qty" plus the "Release Qty" to give you a total order quantity to date.

- The 'Pending Qty' column on the SOMS form shows other orders (not the one currently being viewed) that are on SOMS block for the same customer and product. This is to make the MDA aware of other order quantities in the system. The MDA should take the 'Pending Qty' into consideration when completing the analysis of the current order (the one being viewed).
- When releasing the order the MDA will use the most appropriate reason code for each order.
- If the "MTD Qty" plus the "Release Qty" is equal to or less than the "Customer allow/mth", then customer contact is not required.
- If the "MTD Qty" plus the "Release Qty" is greater than the "Customer Allow/mth", then further analysis is need and SOMS form will need 2<sup>nd</sup> signature from management.

Some of the tools used during analysis:

- Current month call log.
- 852 & 867 data if available.
- Past shipping history; Year over Year (YOY) or Year to Date (YTD) comparison.
- Contact internal departments (i.e. Marketing, Demand Management, and CRA) to verify if they had information to assist in the analysis (i.e. Updated forecast, special orders, short-date, etc...).
- Customer contact.
- When contacting the customer via email, the following verbiage should be used.
  - Subject: "*Company Name* Order(s) on Hold
  - Body of email:
    - *Hi (Addressee(s)), in accordance with 21 CFR 1301.74, we are required to conduct independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed today has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern. In an effort to expedite the investigation process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.*
    - *PO#*
    - *NDC#, Mat#, QTY*
    - *Please note the entire order is on hold. Your quick response will ensure your entire order will be released in a timely manner.*

*Salutation*

- The 'Release Qty' column on the SOMS form will need to be filled in by the MDA; this is the quantity that the MDA releases. Usually the 'Release Qty' is the same as the 'Order Qty', unless the customer requests to reduce or cancel the order or the MDA determine the quantity should be reduced with Management approval.
- If the customer decides to reduce or cancel the order, the MDA will make the appropriate changes to the order when releasing the SOMS block. The MDA will request a reason for the reduction or cancellation of the order. Also, depending on the cancellation reason the MDA may forward the cancellation request to DEA Affairs for review. Please note: For IMA customers, if an increase is requested by the customer, the customer would need to be referred to the customer's CRA to have that request completed, and the increased order quantity will go through IMA again. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Watson in order to streamline their inventory.)
- If the customer is contacted, the MDA will attach supporting documentation to the SOMS form which will include the customer contact name, phone number and/or email, reason for the increase, PO#, SD#, and date of order, and the SKU/Material number and description of the product released. If the same SKU/Material suspends again in the same month, the MDA will determine if the original resolution is appropriate for subsequent orders or if further analysis is needed.
- If the customer decides to reduce the order quantity, the order may come off of SOMS violation hold automatically once the change has been made. If the order appears on the VA05 list after the change, then the MDA will need to evaluate the SOMS form again per standard procedures. Also if the customer decides to cancel the order, then the order may come off of SOMS violation. The MDA will need to execute the VA05 again to verify the order is not on the VA05 list.
- The MDA group should make an effort to get to know the customers and their customers. With that said, if the customer's response is a general response, i.e. increase due to new customers; it is recommended the MDA try to obtain the name, city, & state in which the new customer is located. Please know, the customer has the right to deny this request.

Once this SOMS form is confirmed and verified, the MDA will release the SOMS violation block.

Otherwise, the MDA will escalate the 'order of interest' (SOMS) to the DEA Affairs department for review and feedback. If DEA Affairs determines the 'order of interest' (SOMS) needs to be communicated to the DEA. Then DEA Affairs will contact the DEA.

# A Watson Pharma, Inc.

## ***Call Center Operations*** ***Master Data / License Admin. Operational Procedure***

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<b>Revision Number:</b>	<b>GUROPDALAR 507001.003</b>	<b>Effective Date:</b>	May 5, 2004
<b>Revision Written By:</b>	Larry Shaffer Mary Moskello Victoria Lepore	<b>Revision Date:</b>	January 5, 2012

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### B. Filing: Record Retention:

- Class 2 and 2N's are filed in a separate filing cabinet. The DEA requires all Class 2 and 2N's to be filed separately from the 3, 3N, 4 and 5. All SOMS are filed by the account name, account number, City and State, by most current date. If within the same day there are multiple SOMS, then the most current Sales Document number is filed on top.

Also, there are four states Kansas, Kentucky, New York and Rhode Island which DO NOT allow CONTROLLED samples sent to ANY practitioners.

NOTE: If the customer requests to cancel the order or reduce a line quantity of a Class II (CII) order, an email of the change must be sent to Dept. Coordinator II in Gurnee.

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### **C. License for One Time Customer:**

The Master Data group will create a one-time Master Data template (shell) only once, as necessary. This shell will be used to create orders for one-time customers. A one-time customer shell will be used by order processing to create orders for situations where a permanent Master Data record is not needed, such as Tradeshows or Replacement Orders. A One-time customer shell **SHOULD NEVER** be used for any site order or control substance order. A Customer Master account must be set up in order to place these order types. These templates do not include entry of financial (company-level) data; as such, its usage should be restricted to free of charge orders (i.e., samples, literature etc.). If the one-time customer shell is used to generate a sales order, this record will supply basic customer master information and requires the order processing user to input key fields (i.e., name, address etc). The Master Data group will create the appropriate license for a one-time customer and link the license to the one-time ship-to customer's sales order.

### **D. Unlicensed Locations:**

If a representative receives an order for prescription drugs for an unlicensed location, he/she must obtain the license of an individual who will accept responsibility for drugs being shipped to that specific location.

Such customers may include:

- Dialysis Centers
- Universities
- Health Organizations
- Clinics
- Humanitarian Aid
- Family Planning/Planned Parenthood

The account will then have the Facility's name in name 1 and the responsible doctor's name in name 2, the facility's address. The responsible doctor's state license will be attached at the account level.

In the event the request is submitted with a Mid-Level Practitioner's license, the Master Data Administrator (MDA) will verify that the Mid-Level practitioner is able to receive product by reviewing the Buzzeto PDMA quarterly spreadsheet by logging into the Dendrite website, State Monitor section. The Mid-Level Practitioner's name will then be on name 2 of the account.

On occasion an order will come in for an unlicensed Watson facility. When the order comes in it will go to License Block (VE31). In order to release this order from license block, a mock license will need to be created; the license will only be valid for one business day. Once the order has shipped the license will be expired. Only a State License with a the single schedule of RX (no controls) will be created, the license number will typically be the first six characters of the city of the unlicensed facility or enough characters to be able to distinguish the location. For example if the order was going to Parsippany, NJ the license number would be PARSIP. The license will be attached at the account/Master Data level. If the order is for a TRADESHOW a mock license will be created as stated above except the license number will be "TRADESHOW".

On occasion we will receive an order from the FDA for Samples which the FDA does not have a State Board of Pharmacy license. If this is the case, you will need to create a 1 day State license with the external license number with the word FDA followed by the 10 digit telephone number (i.e. "FDA3123535863"). Expire the license once the DD# has been created.

### **E. Methamphetamine Control Act:**

The Master Data Administrator (MDA) will create a valid DEA or State license for any Meth Act products. The DEA license is preferred; if DEA is not available the State license will be used. The system will display the DEA or State license on the packing slip for all Watson products; this is done to be in compliance with State regulations.

### **F. Indigent Accounts:**

Quarterlies (As of 4/2007, DaVita Healthcare is the only customer of this sort)

These customers place orders on a quarterly basis and the account should be created in the clinic's name. These clinics usually do not have a license of their own so the account will then have the Facility's name in name 1 and the responsible doctor's name in name 2, the facility's address and the responsible doctor's state license attached at the account level. In the unlikely event that a clinic has its own license, the account will be created in the clinic's name and the clinic's license will be linked at the customer master level.

#### Dailies

These customers place orders on a daily basis and the account should be created in the physician's name, even if his office is located in a hospital or clinic. If the physician wants to ship goods to numerous locations, a Sold-To should be created for the primary location and Ship-To's should be created for the additional locations. All accounts are to be linked to the same state license even if the address does not match the license as long as this does not violate PDMA regulations. Note: The Sold-To address is usually the address that is on the physician's state license, but the physician may choose not to ship goods to the address listed on the state license, in this case the physician will choose another address as the Sold-To. If, at a later time, the physician wants to ship goods to the address listed on the state license, that account may be created as a Ship-To and linked to the existing Sold-To.

#### Trelstar and Indigents

Trelstar and Indigent orders are top priority and should be released as soon as possible following standard procedures.

### **G. PapSure Physician Address Changes:**

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NOTE: You do not need a license for PapSure orders, since the Material master record considers PapSure as an OTC product, therefore, the order should not be held up for a license.

### **H. R&D Research and Development:**

This section may pertain to Clinical Research, Calibration and Marketing Demonstration Requests. In-house shipments for prescription items to facilities for research and/or development purposes do not require licensing. Please refer to "Unlicensed Locations" section for in-house shipments. Shipments going to outside companies require a valid State or DEA license. **Exhibit A - NTIS National Technical Information Services**

The screenshot shows the homepage of the DEA Controlled Substances Act Database. At the top, there's a banner for 'GIM.net' and 'NTIS'. Below the banner, there's a 'SUBSCRIBER LOGIN' section with fields for 'USERNAME' and 'PASSWORD'. To the right, there's a 'LATEST NEWS' section with a link to 'NTIS and GIM.net Announce Re-Launch of deanumber.com'. Below the news, there are two main sections: 'Controlled Substances Act (CSA) Registration Database' and 'The Controlled Substances Act of 1970'. The CSA registration database section includes a note about Verisign security and a statement that it's the official DEA authorized database. The controlled substances database section provides a brief history and details about the database's purpose. At the bottom, there's a search form titled 'Drug Enforcement Administration (DEA) Controlled Substance Act Registration Information Online Search - As of March 11, 2004' with various search criteria fields like 'List Type', 'DEA #', 'Business Activity Code', 'Company / Doctor Name', etc., and 'Search' and 'Reset' buttons.

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Exhibit A – NTIS continued...

DEA Number	Exp. Date	Company Name	State	Zip
AC0393734	8/31/2005	CITY PHARMACY INC	TN	37745
AT7665637	11/30/2005	SUSONG PHARMACY	TN	37745
BS0143850	2/28/2007	STUMM, HARRY J MD	TN	37745
BP3389093	3/31/2007	PATTERSON, MARK DAVID MD	TN	37745
MM0269365	1/31/2005	MCMILLIAN, JEFFREY OD	TN	37745
MR0852081	4/30/2005	ROBBINS, MELISSA A FNP	TN	37745
MM0467426	1/31/2006	MORRISON, REBECCA A PNP	TN	37745
MP0551033	3/31/2006	PACE, NANCY L NP	TN	37745
MC0649472	8/31/2006	CARRINO, THOMAS PA	TN	37745
BW8300220	5/31/2004	WALGREEN CO	TN	37745
BT4966200	11/30/2004	THE MEDICINE SHOPPE	TN	37745
AC0401202	12/31/2004	REVCO DISCOUNT DRUG CTRS, INC	TN	37745
AR0276405	12/31/2004	REVCO DISCOUNT DRUG CTRS, INC	TN	37745
BF8029589	9/30/2005	FOOD CITY PHARMACY #606	TN	37745
BH2489032	10/31/2005	HOWARD'S PHARMACY	TN	37745
BR3339618	6/30/2006	RITE AID OF TENNESSEE INC	TN	37745
BG8618689	9/30/2006	GREENE COUNTY DRUG STORE, LLC	TN	37745

Select the hyperlink that matches the DEA information

searching for.

 In joint venture with   
 National Technical Information Service  
One Source. One Search. One Solution.

Current Date: 3/15/2004      Data File Release Date: March 11, 2004

**Drug Enforcement Administration (DEA) Datafiles -Both**

**Registrant Profile**

for

<b>CITY PHARMACY INC</b>	
Address:	113 E CHURCH ST GREENEVILLE, TN 37745
State / Zip:	TN 37745
DEA Number:	AC0393734
Business Activity Code:	A
Drug Schedule:	22N 33N 4 5
Expiration Date:	8/31/2005

Standard Abbreviations	
CRA	Customer Relations Administrator
DEA	Drug Enforcement Administration
MDA	Master Data Administrator
MTD	Month to Date
NTIS	National Technical Information Service
PDMA	Prescription Drug Marketing Act
SOMS	Suspicious Order Monitoring System (of Control Drugs Substances)
YOY	Year Over Year
YTD	Year To Date